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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,126	09/19/2003	Richard C. Conrad	AMBI:086US	7162

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EXAMINER	
KIM, TAEYOON	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,126	CONRAD, RICHARD C.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *1-41,48-53 and 56-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-47,54 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/05, 12/19/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-57 are pending.

Election/Restrictions

Applicant's election with traverse of Group II (claims 42-45) in the reply filed on Nov. 28, 2006 is acknowledged. The traversal is on the ground(s) that Groups I-IV and VI fall into the same classification and no proof of undue burden of the search all Groups together. This is not found persuasive because search burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Searching the instant (Groups I-IV and VI) patentably distinct inventions would, in fact, impose a serious burden on the examiner. If applicants admit on the record that Groups I-IV and VI are obvious over one another, the Groups will be rejoined, since a single search would suffice for all Groups. By so admitting, applicants stipulate that if a reference is considered prior art over one Group, it shall be considered prior art over all (Groups I-IV and VI) Groups. Applicant argues that these methods are similar sharing many of steps between them. However, there are steps which are not shared between these Groups of inventions, and therefore, adding further burden to search additional steps differentially required by an individual Group of invention. For example, the step (c) of Group II invention is not required by the method of Group I invention, or the step (a) of Group I invention is not required by the method of Group II invention. Moreover, the limitations to the Group I invention (e.g. claims 2-41) are not disclosed in the method of Group II or III invention.

In fact, the different Groups of the current application have distinct limitations

which are not shared by each and every group, and therefore, impose a serious search burden for each limitation given in each individual Group of invention.

The requirement is still deemed proper and is therefore made FINAL.

However, the Group III invention has been rejoined with the Group II invention. Therefore, claims 1-41, 48-53 and 56-57 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 42-47 and 54-55 have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 recites the limitation "the eluted sample" in first line. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 42-47 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugharn et al. (US 6,111,096) in view of RNA STAT-60 Reagent (internet article), in further view of Moss (2001) and Ambros (2001).

Claims 42-47 and 54-55 are drawn to a method for isolating miRNA or siRNA from a sample comprising a) obtaining a sample having miRNA or siRNA, b) adding an alcohol solution to the sample, c) adding an extraction solution to the sample, d) applying the sample to a mineral or polymer support, and e) eluting the siRNA or miRNA from the support (claim 42); a limitation to the sample being a cell lysate (claim 43); a limitation to the cell lysate being produced by adding a lysing solution comprising a chaotropic agent or detergent to the cells having miRNA or siRNA (claim 44); a limitation to the eluted miRNA or siRNA being enriched at least about 10-fold by mass (claim 45); a method for isolating miRNA from a sample comprising a) adding an alcohol solution to the sample, b) applying the sample to a mineral or polymer support, c) eluting the siRNA or miRNA from the support, and d) using or characterizing the miRNA molecules (claim 46); a limitation to the sample of claim 46 being a cell lysate (claim 47); a limitation to the elution being with an ionic solution (claims 54 and 55).

Laugharn et al. teach a method of purifying nucleic acids comprising having a cell lysate obtained by lyzing cells with a chaotropic agent such as RNA Stat-60 which contains phenol and guanidinium thiocyanate (see p. 1 of RNA STAT-60 Reagent; http://www.isotexdiagnostics.com/rna_stat-60_reagent.html), precipitating RNA by adding isopropanol, adding a solution containing ethanol and TX-100 (extraction solution), applying the sample to DEAE resin column (mineral or polymer support), and

eluting RNA from the support with an ionic solution containing sodium chloride in Tris buffer (see Example 4). Laugharn et al. also teach the quantification (characterization) of eluted nucleic acids (RNA) by using Oligreen DNA binding dye or analysis by agarose gel electrophoresis, UV spectroscopy (see Examples).

Although Laugharn et al. do not specifically teach the method is intended for isolating miRNA or siRNA, Laugharn et al. teach that the method can be used for isolation of small nucleic acids (for example, less than 50 bp) (see column 4, lines 32-33). Since the size of miRNA and siRNA are about 22 bp. as evidence by Ambros (2001) and Moss (2001), therefore, the method of Laugharn et al. can be used for the isolation of miRNA or siRNA.

Although Laugharn et al. do not teach the fold enrichment of miRNA or siRNA after elution being at least about 10 fold, it would have been obvious for a person of ordinary skill in the art to optimize routinely to obtain higher enrichment of RNA by the method of Laugharn et al. The selection of at least 10 fold enrichment of RNA samples would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that higher yield (enrichment) of RNA isolated/purified by a method of Laugharn et al. would be a key objective in any purification method. A holding of obviousness over the cited claims is therefore clearly required. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of fold enrichment ranges is the optimum combination of ranges. See *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382.; See also M.P.E.P. § 2144.05.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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